Trials@Home proof-of-concept study RADIAL is ready for patient recruitment

21st June 2023

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

Disclaimer

The research leading to these results was conducted as part of the Trials@Home consortium.
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Trials@Home project

The aim

Provide recommendations on Decentralised Clinical Trials (DCTs) in Europe

Project start September 1, 2019, due to end August 31, 2024

The consortium

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Agenda

Topic	Presenter	Time
Welcome	Petra Naster	15:00 - 15:05 *(5 min)*
The *why* and *how* of RADIAL	Mira Zuidgeest	15:05 - 15:15 *(10 min)*
The co-creation of RADIAL	Megan Heath & Sabine Dupont	15:15 - 15:25 *(10 min)*
Decentralised Elements and Technology	Bart Lagerwaard	15:25 - 15:35 *(10 min)*
Q&A	Petra Naster	15:35 - 16:00 *(25 min)*

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The *why* and *how* of RADIAL

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Presenter

Mira Zuidgeest

Associate Professor

University Medical Center

Utrecht, NL

Academic lead Trials@Home &

RADIAL PI

The *why* of the T@H RADIAL proof-of-concept study

RADIAL **aims to assess the scientific and operational quality of a fully decentralised and hybrid trial approach compared to a conventional trial approach**

Primary study objective 1

To explore potential benefits of DCT approaches on participant recruitment, retention, diversity, site and patient satisfaction, and cost.

Primary study objective 2

To evaluate acceptability of DCT approaches by measuring variables related to safety oversight, treatment adherence and data quality

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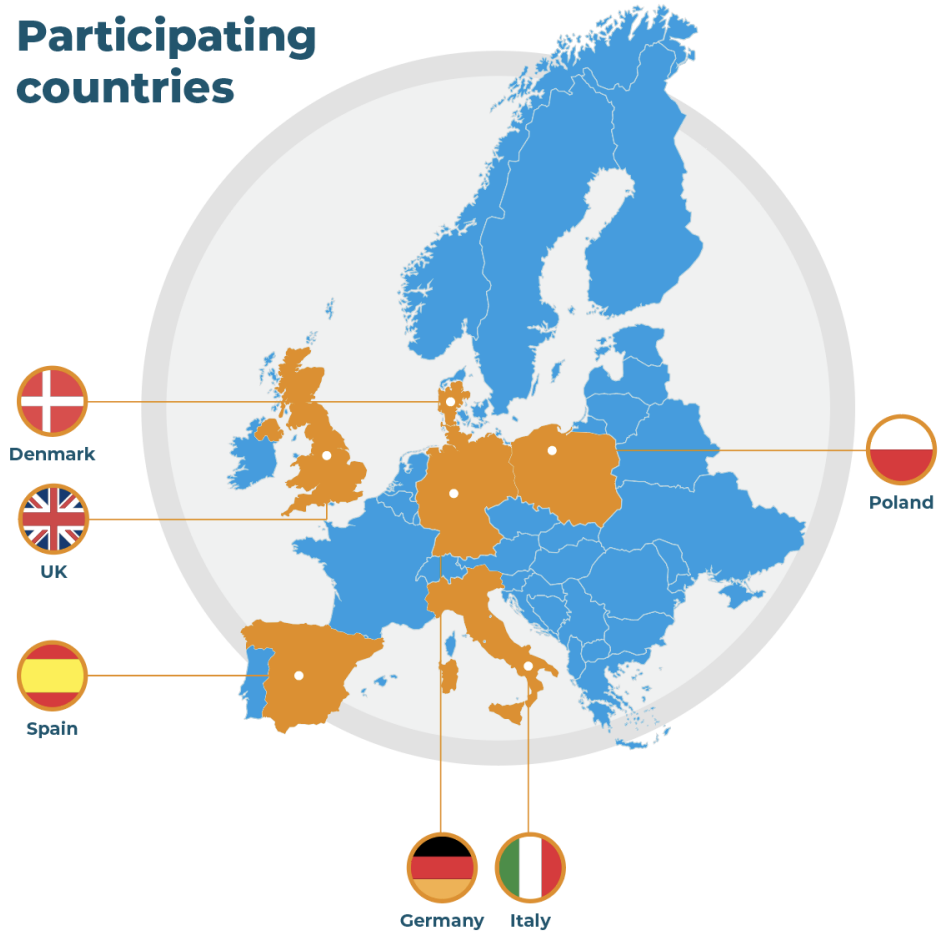
The *what* of the T@H RADIAL proof-of-concept study

- Pan-EU, Parallel-group, open-label, multi-centre study
- People with type 2 diabetes (with Hb1Ac 7-10%)
  - Switch long-acting insulin
  - Phase IV study
- Composed of 2 parts with 3 different arms:
  - **Part A** - Site-based recruitment
    - Conventional arm (x150)
    - Hybrid arm (x150)
  - **Part B** - Recruitment performed remotely
    - Remote arm (x300)



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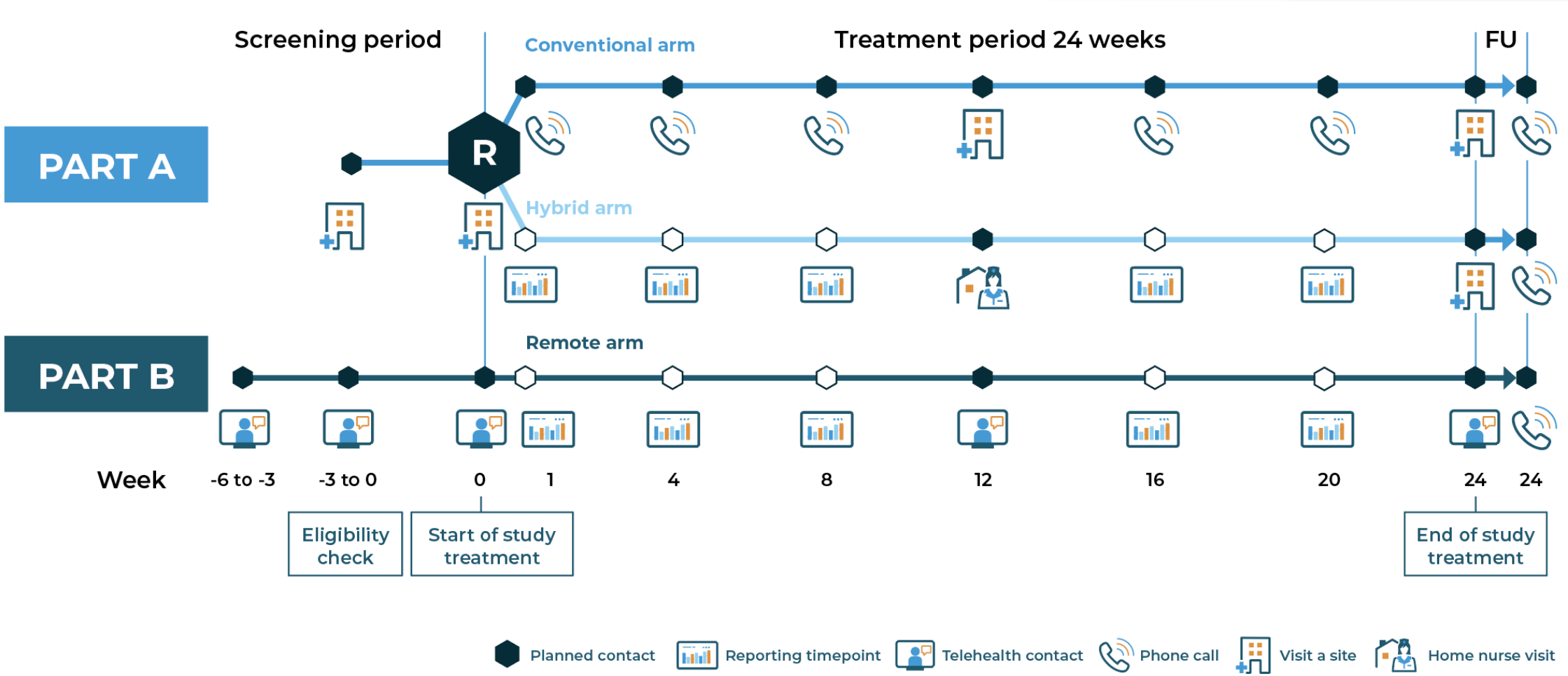
The *how* of the T@H RADIAL proof-of-concept study



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Important RADIAL features

Approved proof-of-concept study	Low intervention phase IV trial	Population familiar with insulin
Methodological objective with KPIs as main outcomes	IMP used within the market authorisation label	People with type 2 diabetes with Hb1Ac 7-10% already using long-acting insulin

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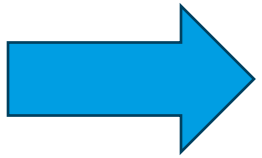
Key Performance Indicators as main outcomes

Hybrid and DCT approaches need to meet the same **Key Performance Indicators (KPIs)** as conventional trial approaches for generating **valid and appropriate data** to allow drawing appropriate conclusions from the study results



The RADIAL study will focus on the characterisation and evaluation of recognised **KPIs which reflect scientific and operational quality of clinical trials**

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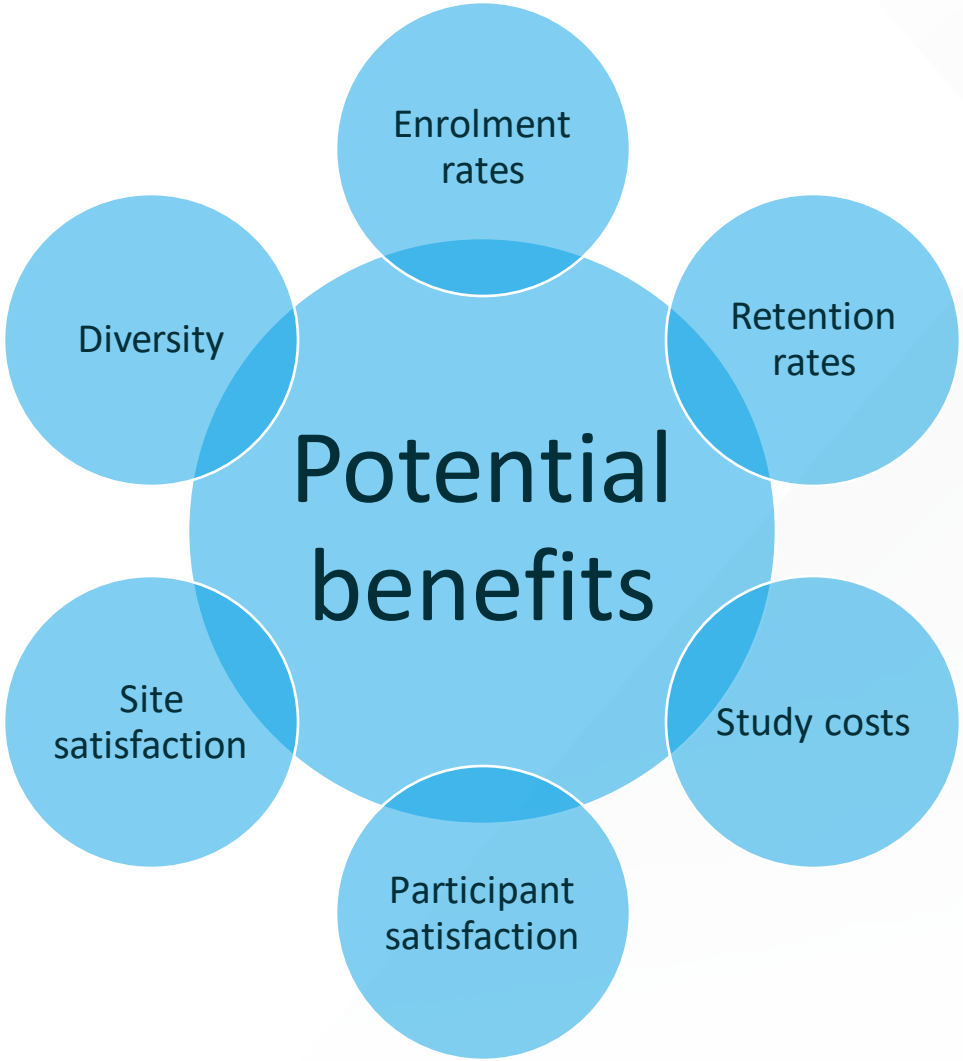
RADIAL primary study objective 1

To explore potential benefits of DCT approaches on participant recruitment, retention, diversity, site and patient satisfaction, and cost.



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RADIAL primary study objective 2

To evaluate acceptability of DCT approaches by measuring variables related to safety oversight, treatment adherence and data quality

Delphi expert panel to determine threshold levels of acceptability for these KPI for this study

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The Co-Creation of RADIAL

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Presenters

Sabine Dupont

Director Policy & Strategy

International Diabetes

Federation Europe

IDF Europe Lead

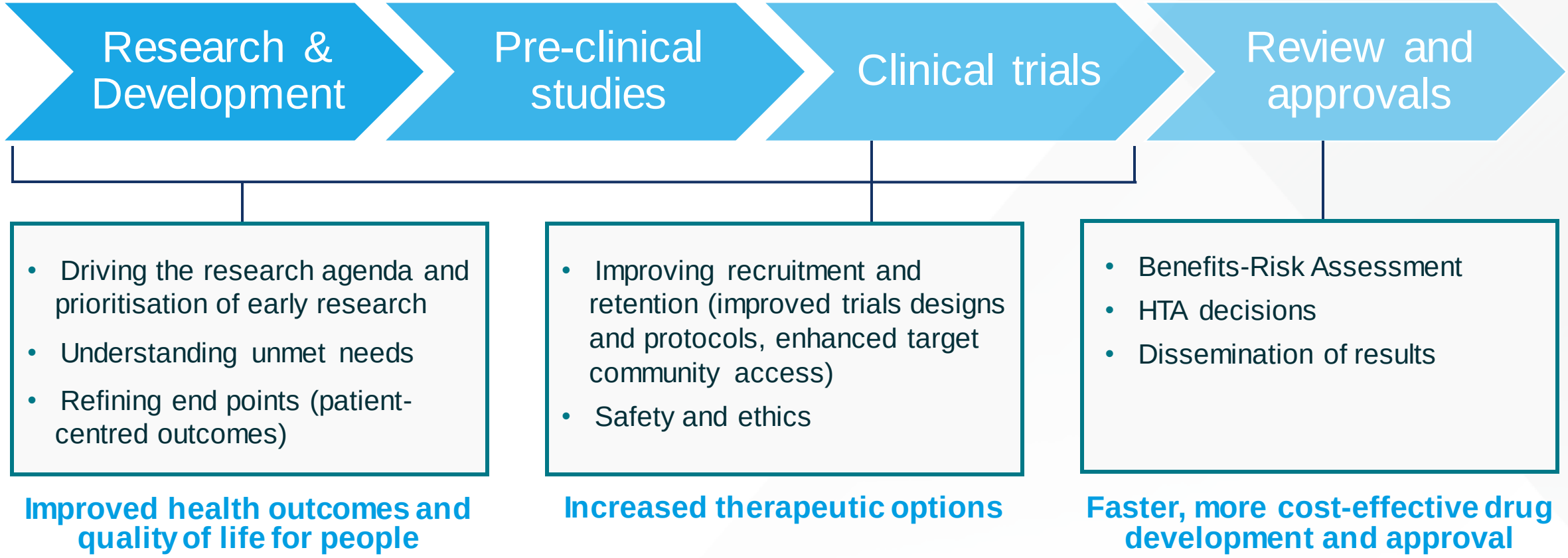
Megan Heath,

Head Clinical Study Units

Europe Region,

Sanofi

How are people with lived experience engaged in research projects – roles and benefits



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How PwD participate in Trials@Home – The Patient Expert Panel

The Patient Expert Panel (PEP) is composed of **seven PwD** representative of the community in Europe plus **one IDF Europe coordinator**:








PEP PATIENT EXPERT PANEL

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How PwD participate in Trials@Home – The Patient Expert Panel

The PEP provides advice, insights and inputs into all Trials@Home Work Packages through ongoing, regular participation as well as through special projects/initiatives.

The PEP ensures that the experiences, needs and perspectives of people living with diabetes are reflected **at all stages** of the research and project development process and during the dissemination phase.

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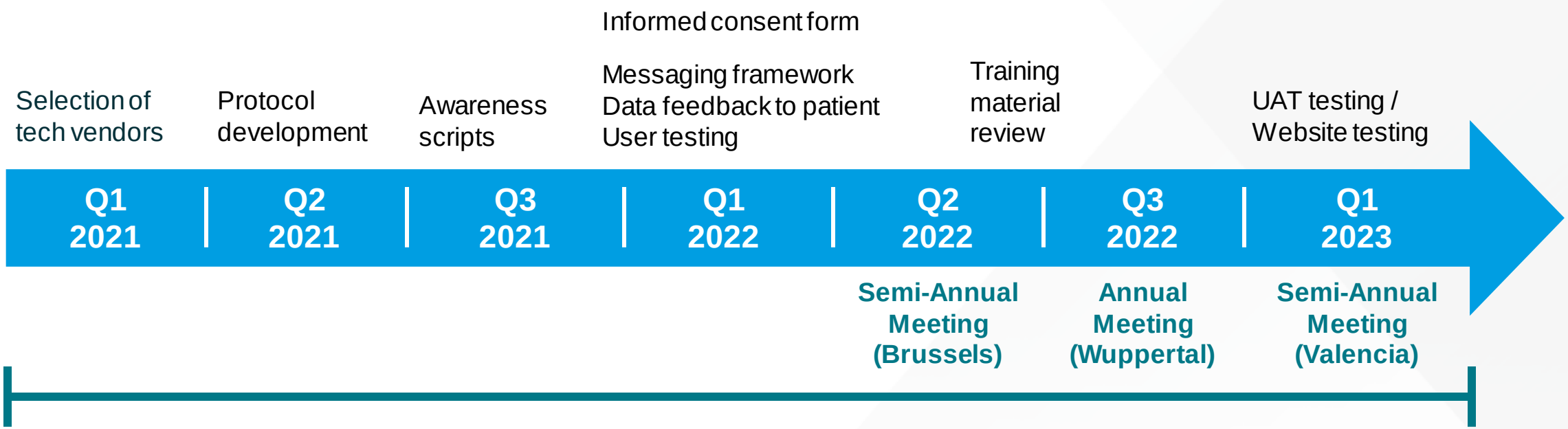
PEP Engagement – structure & examples



Active participation of the PEP throughout the project, embedded in **WP2**, **WP3**, **WP4** and **WP5** and in **Annual/Semi-Annual Meetings**

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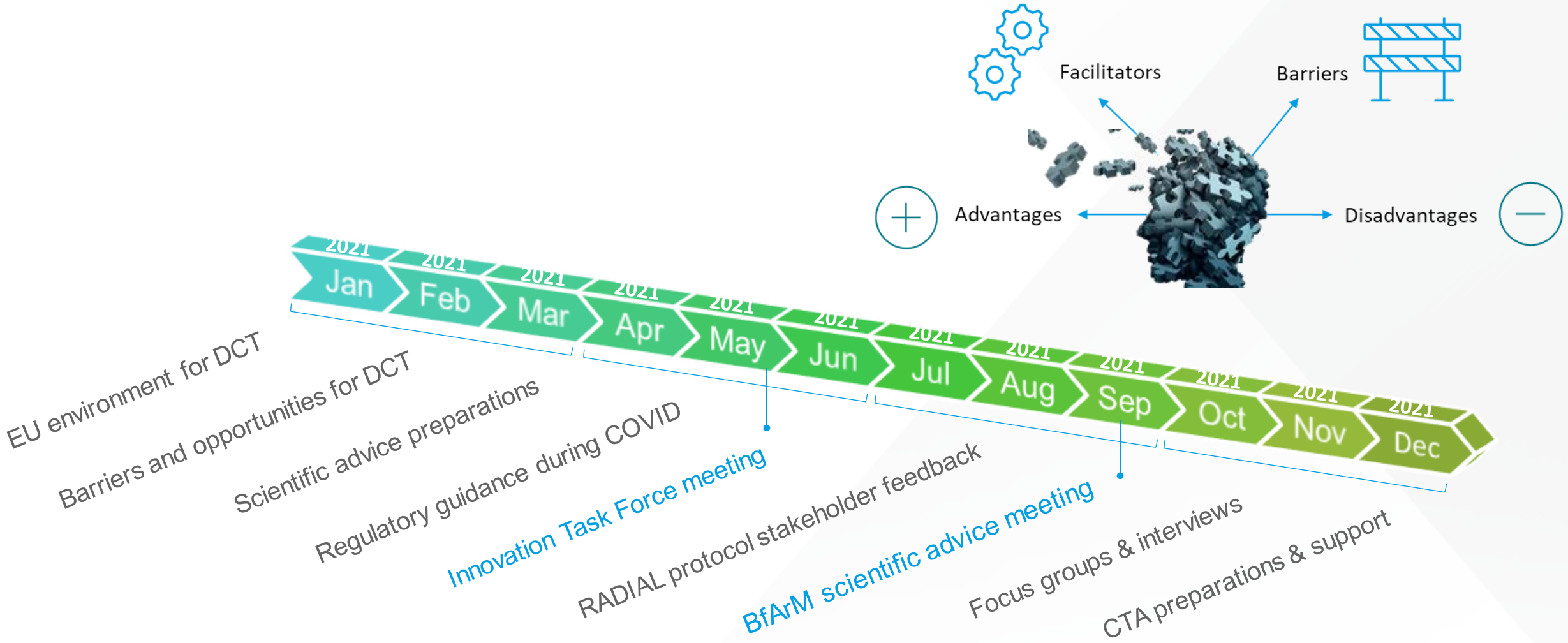
Our Co-Creation Journey



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Summary of key Regulatory considerations for DCT

Onboarding, training & consent

- Compliance with divergent national regulations in a heterogenous EU environment

Investigator responsibilities per ICH GCP

- Need to ensure adequate Investigator oversight of remote participants, personnel and procedures

Safety and efficacy

- Adverse event reporting in remote setting, comparability of assessments in clinic vs. at home

Data integrity, participant rights & privacy

- ID verification, appropriate data access & hosting, GCP compliance & inspections

Decentralised Elements & Technology

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Presenters

Bart Lagerwaard

Assistant Professor

University Medical Center Utrecht

Scientific coordination RADIAL

Decentralised elements in RADIAL

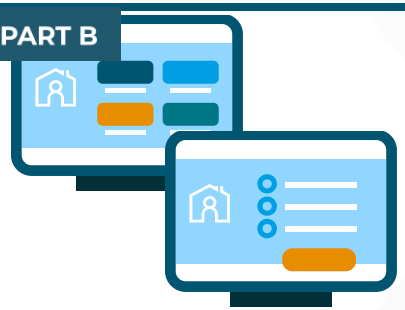
PART B

eConsenting and eSignature

PART B

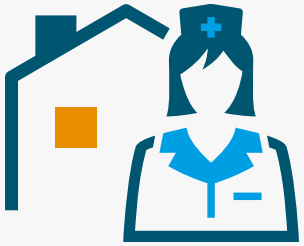
Telemedicine

PART B



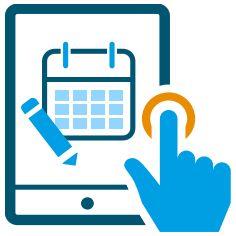
Online recruitment and pre-screening

PART A



Home nurse visits

Remote monitoring IMP adherence



Study app for reporting (S)AEs and ePROs

Direct to patient shipment of IMP

At home sample collection

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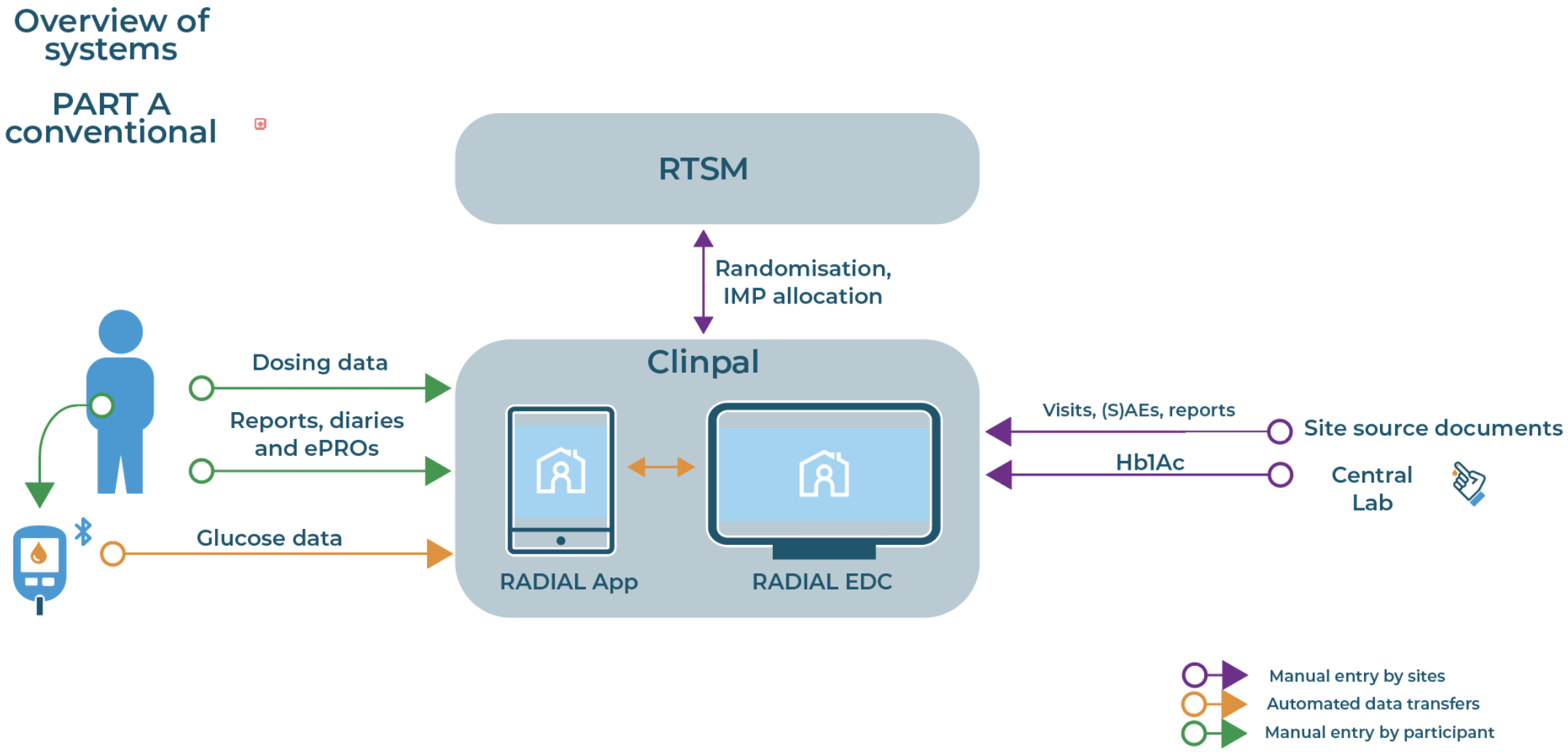
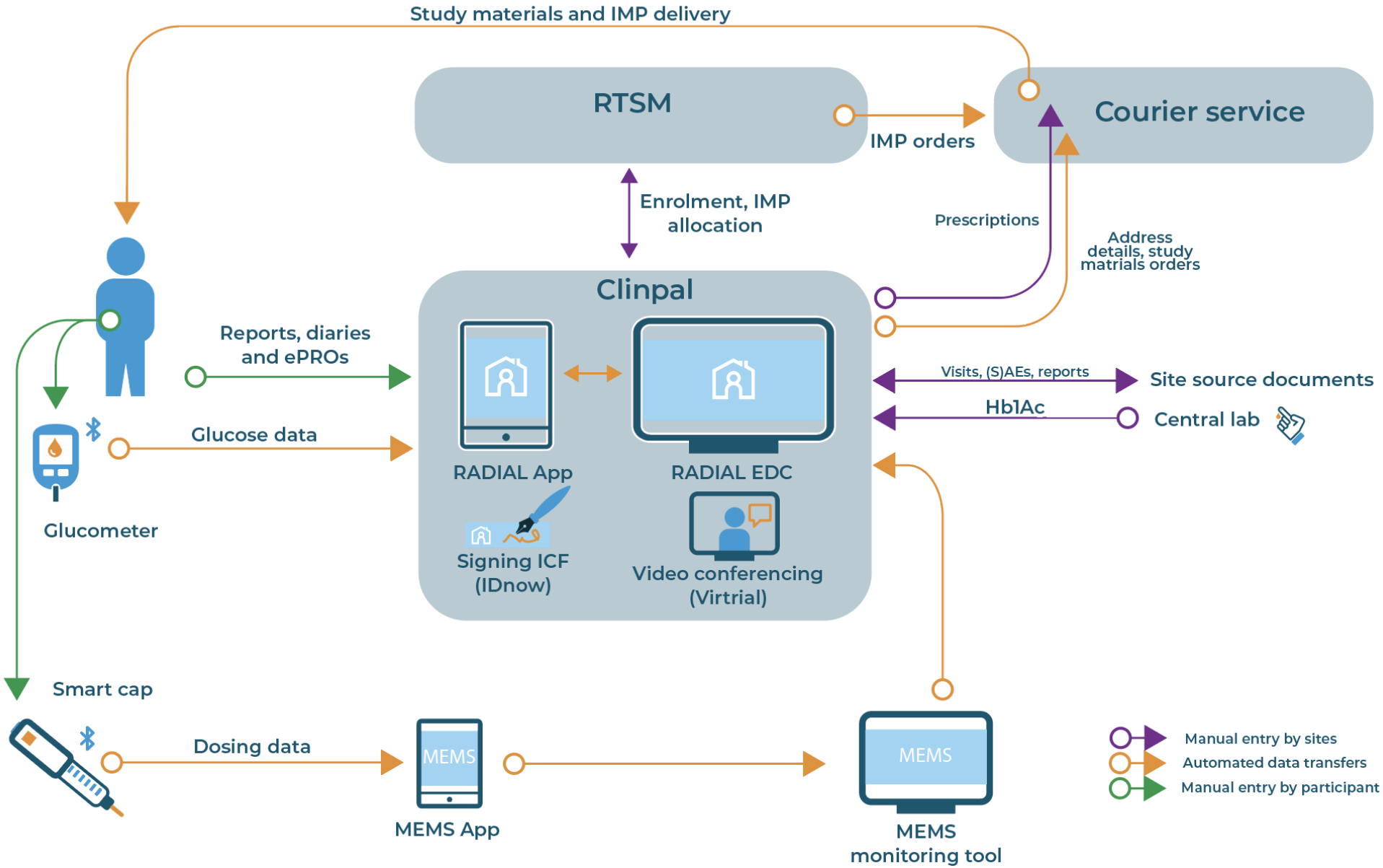
Decentralised elements and complexity …



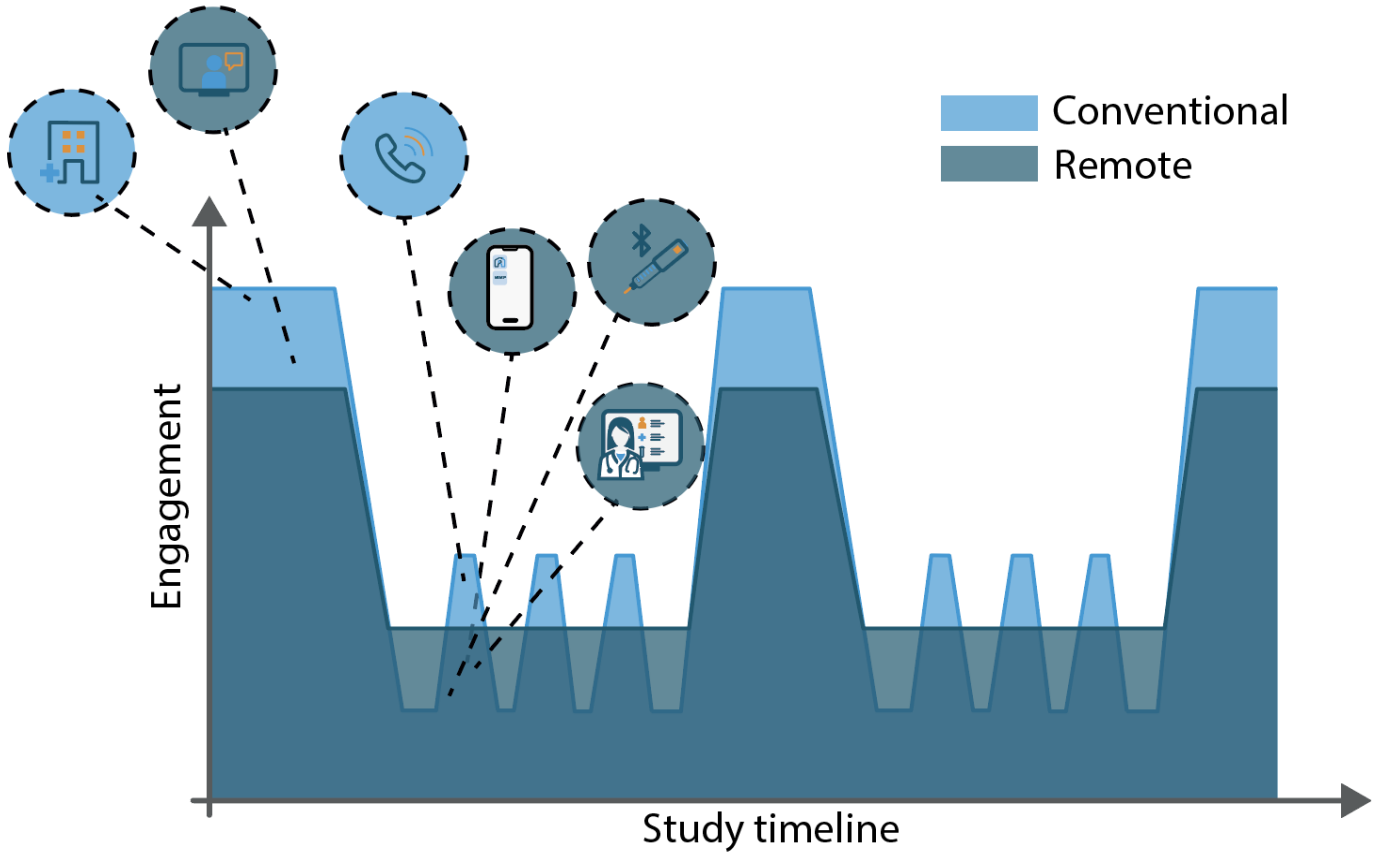
Overview of systems

PART B



Investigator oversight in a DCT (RADIAL)

- In a conventional trial, the participant is most of the time 'remote' (not at the clinical trial site).
- Using (novel) technology the remote participant can be brought 'closer' to the investigator



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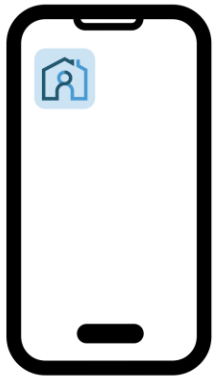
How to maintain oversight when participants are remote?

- In decentralised/hybrid arm, the investigator has access to tools to maintain oversight – even though the participant does not physically visit the site.



Continuous reporting

Remote

Data collection

Remote

monitoring

(Ad hoc)

Telemedicine or phone call

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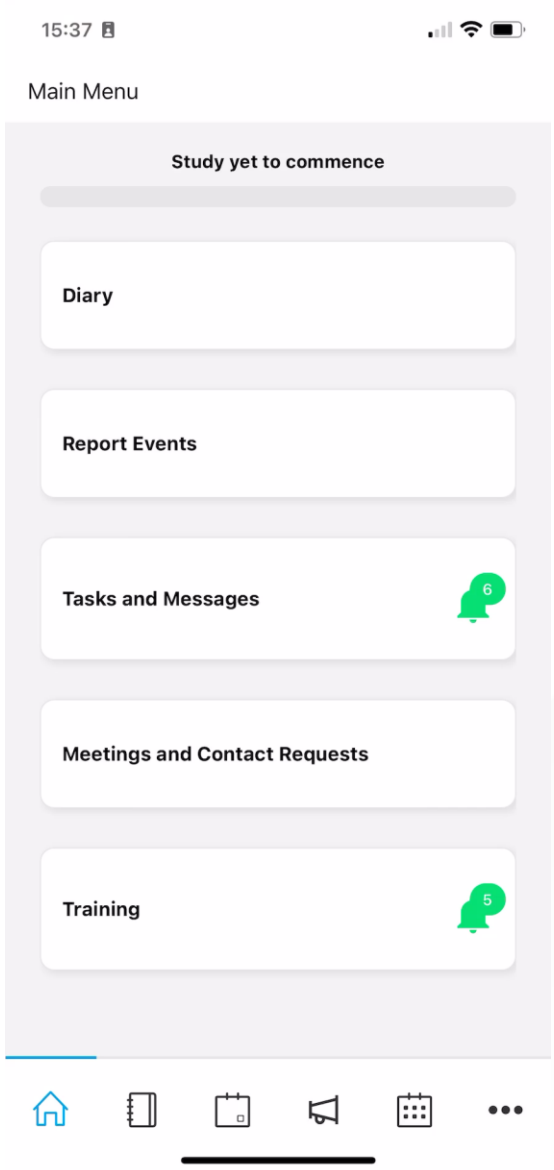
Continuous reporting



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Remote data collection and monitoring

MAIN MENU

- Home Page
- Patients list 7
- Help

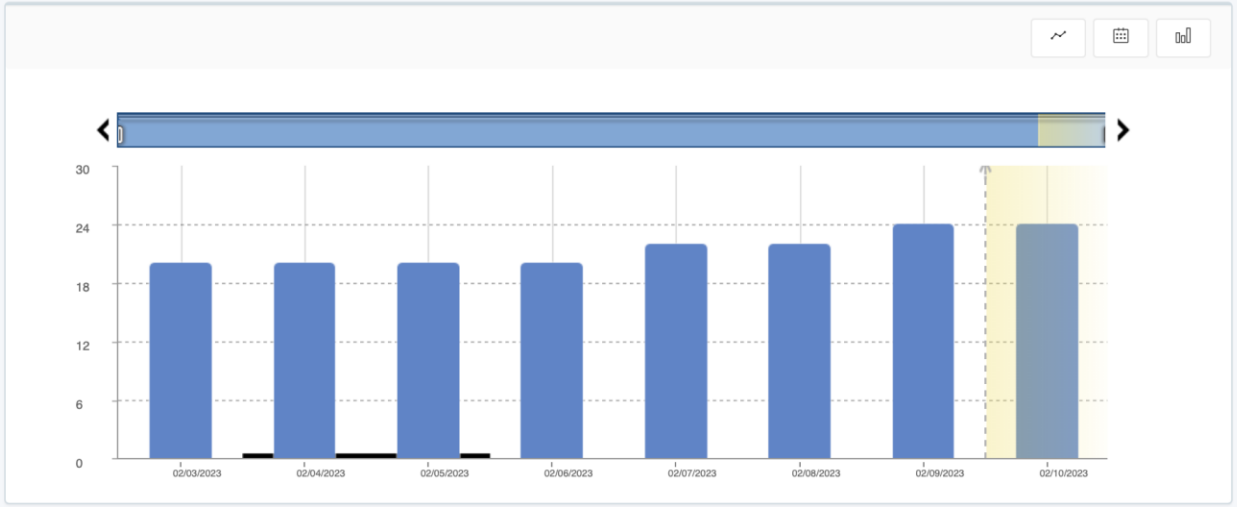
Custom filters

Patients | Adherence status

(All sites) | Quick search | Refresh

Drag a column header and drop it here to group by that column

Site	Patient code	CID	Last read	From date	To date	Adherence level	Last adherence status
995_UseCases	UC1-OK	2c999900	10/02/2023 10:00:07	03/02/2023 00:00:00	10/02/2023 23:59:59	100 %	No deviation
995_UseCases	UC2-SUB	2c999901	10/02/2023 15:00:00	03/02/2023 00:00:00	10/02/2023 23:59:59	0 %	Suboptimal adherence
995_UseCases	UC3-TIT	2c999902	10/02/2023 15:00:00	03/02/2023 00:00:00	10/02/2023 23:59:59	100 %	Potential titration in the last 7 days
995_UseCases	UC4-MAN	2c999903	10/02/2023 15:00				
995_UseCases	UC5-MUL	2c999904	10/02/2023 15:00				
995_UseCases	UC6-ABS	2c999905	05/02/2023 15:00				
995_UseCases	UC7-DYN	null	null				



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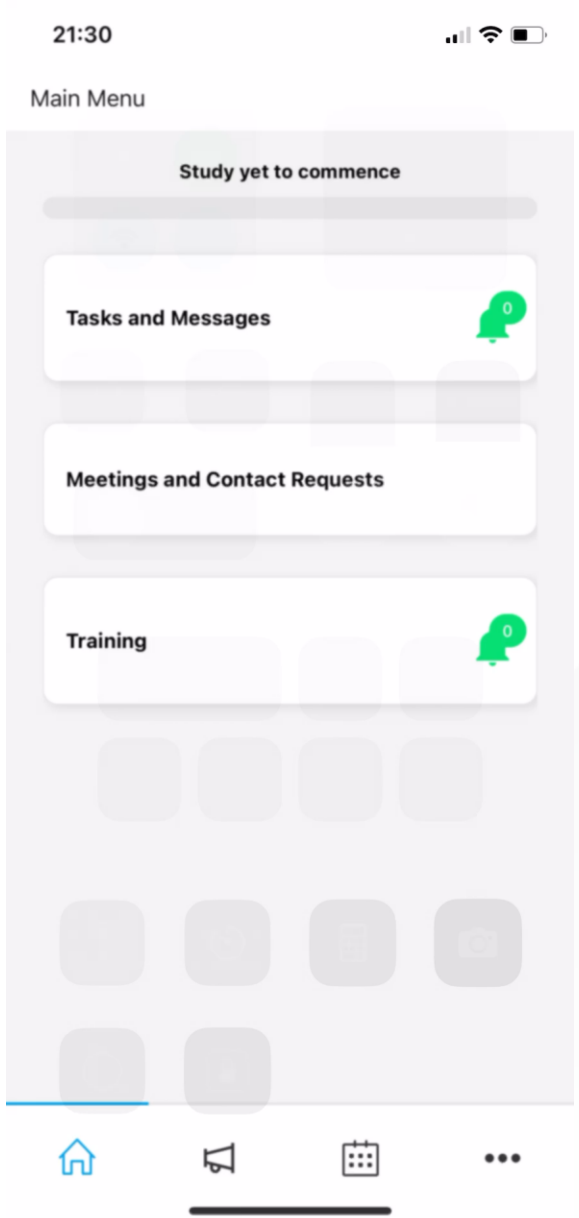
Telemedicine



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A remote site, a 24/7 clinical trial site?

- We cannot expect real-time review and follow-up on collected data and reports
- Risk-based approach
- Expectation management (for both site and participant)

Weekly ‘digests’ of dosing data

Automated alerts and notifications

Reporting timepoints

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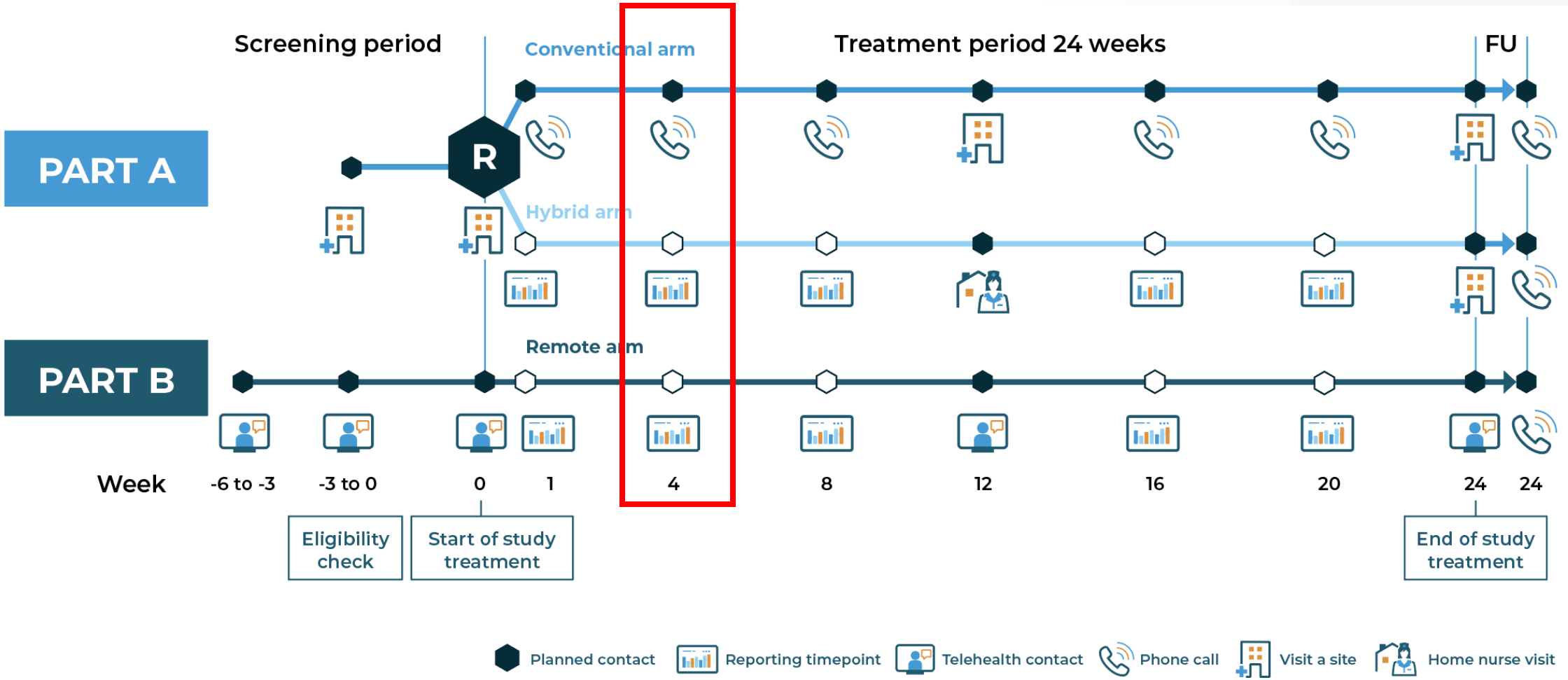
The *how* of the T@H RADIAL proof-of-concept study



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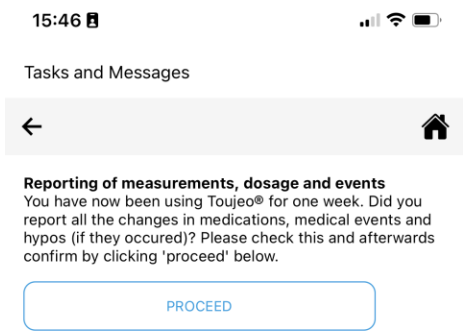
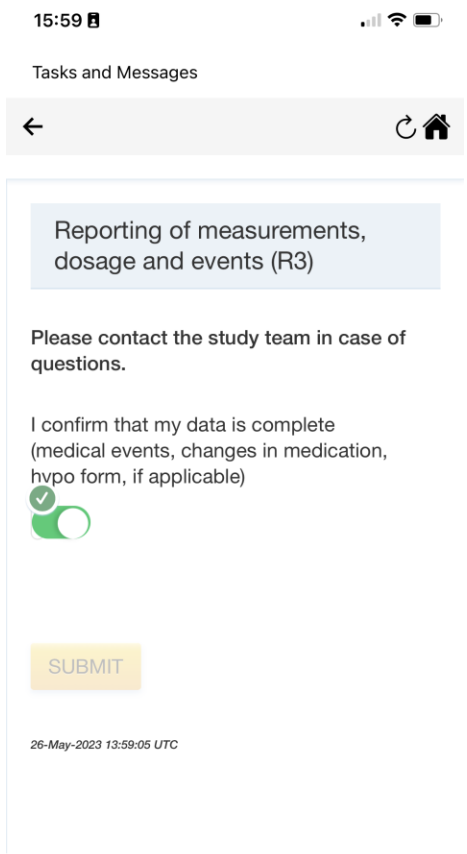
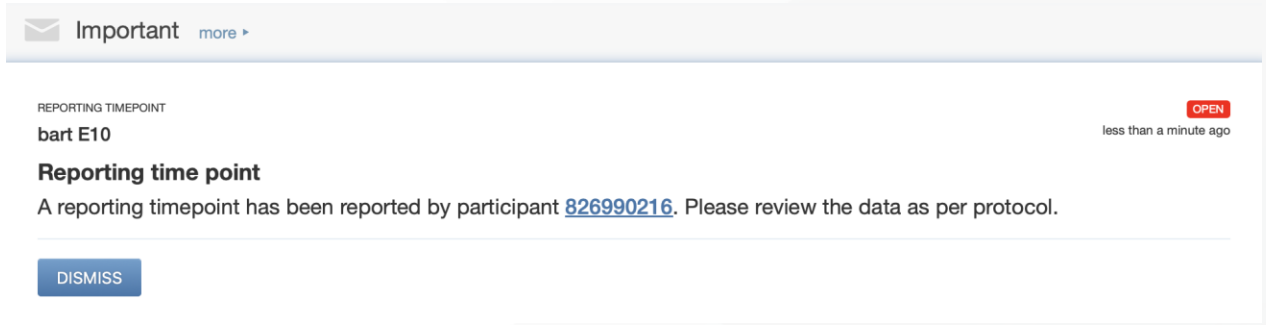
Messaging and Reminders







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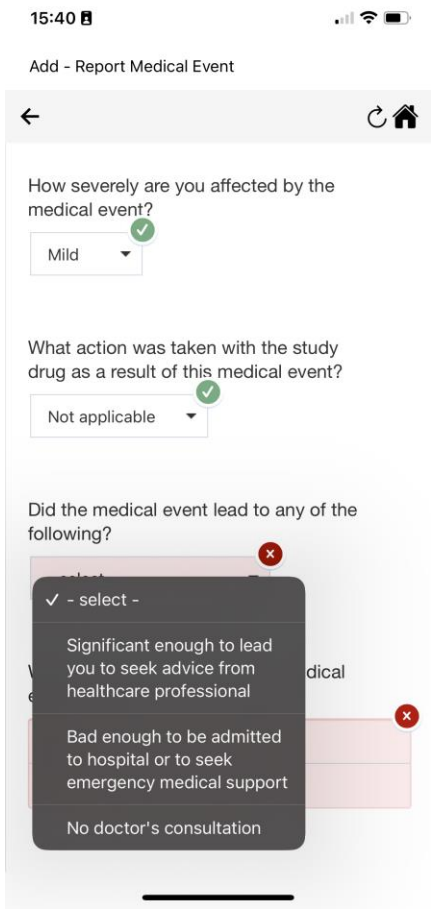
Notifications for Sites



RADIAL

A medical event has been reported by 826990216. It could qualify as a SAE based on the answers filled out in the form. Please review the form.

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Current Status

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Current status

Where are we now?

- Systems are in place and will go live soon
- Logistics all set with one exemption
- SIVs are being conducted

Where are we going?

- First country live: United Kingdom
- Second wave to go live: planned for second half July
- Third wave to go live: planned for August
- Country order depends on contracting & translations

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Shaping the future of clinical trials

Further information on T@H and RADIAL

- Project website www.trialsathome.com
- Contact us at trialsathome@umcutrecht.nl

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Thank you

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